

for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled “Total Nitrogen—Official Final Action” under the heading “Total Solids,” or in section 16.193 (dry sample), entitled “Kjeldahl Method” under the heading “Protein—Official Final Action.”

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), “Reese-Gottlieb Method [Reference Method] (11)—Official Final Action” under the heading “Fat,” or in section 16.199 (dry sample), entitled “Fat in Dried Milk (45)—Official Final Action.”

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled “Ash (5)—Official Final Action” under the heading “Total Solids,” or in section 16.196 (dry sample), entitled “Ash—Official Final Action” under the heading “Dried Milk, Nonfat Dry Milk, and Malted Milk.”

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled “Gravimetric Method—Official Final Action” under the heading “Lactose,” or in section 31.061 (dry sample), entitled “Lane-Eynon General Volumetric Method” under the heading “Lactose—Chemical Methods—Official Final Action.”

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled “Moisture (41)—Official Final Action” under the heading “Dried Milk, Nonfat Dry Milk, and Malted Milk.”

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled “Method I—Official Final Action” under the heading “Total Solids.”

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled “Acidity (2)—Official Final Action” under the heading “Milk,” or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent) as determined by the method described in the “Food Chemicals Codex,” 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(3) The whey must be derived from milk that has been pasteurized, or the whey and modified whey product must be subjected to pasteurization techniques or its equivalent before use in food.

(c) Whey, concentrated whey, and dry (dried) whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The label on the whey form sold to food manufacturers shall read as follows:

(1) For whey: “(Sweet or acid) whey” or “whey (\_\_\_\_% titratable acidity).”

(2) For concentrated whey: “Concentrated (sweet or acid) whey, \_\_\_\_% solids” or “Concentrated whey (\_\_\_\_% titratable acidity), \_\_\_\_% solids”.

(3) For dry (dried) whey: “Dry (dried) (sweet or acid) whey” or “dry (dried) whey, (\_\_\_\_% titratable acidity)”.

(e) Whey, concentrated whey, or dry (dried) whey in a finished food product shall be listed as “whey.”

[46 FR 44439, Sept. 4, 1981; 47 FR 7410, Feb. 19, 1982, as amended at 54 FR 24899, June 12, 1989; 64 FR 1760, Jan. 12, 1999]

**§ 184.1979a Reduced lactose whey.**

(a) Reduced lactose whey is the substance obtained by the removal of lactose from whey. The lactose content of the finished dry product shall not exceed 60 percent. Removal of the lactose is accomplished by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced lactose whey can be used as a fluid, concentrate, or a dry product form.

The acidity of reduced lactose whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The reduced lactose whey meets the following specifications:

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analytical Chemists," 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 16 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 11 to 27 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, not more than 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon

General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the method prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the "Food Chemicals Codex," 4th ed. (1996), pp. 760-761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(3) The reduced lactose whey shall be derived from milk that has been pasteurized, or the reduced lactose whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) Reduced lactose whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of lactose present on a dry product basis, i.e., "reduced lactose whey (\_\_\_% lactose)," shall be declared on the label of the package sold to food manufacturers. The percent of lactose may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of lactose in the product, or as a actual percentage provided that an

## § 184.1979b

## 21 CFR Ch. I (4–1–04 Edition)

analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced lactose whey in a finished food product shall be listed as “reduced lactose whey.”

[46 FR 44440, Sept. 4, 1981, as amended at 54 FR 24899, June 12, 1989; 64 FR 1760, Jan. 12, 1999]

### § 184.1979b Reduced minerals whey.

(a) Reduced minerals whey is the substance obtained by the removal of a portion of the minerals from whey. The dry product shall not contain more than 7 percent ash. Reduced minerals whey is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced minerals whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced minerals whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The reduced minerals whey meets the following specifications:

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 10 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled “Total Nitrogen—Official Final Action” under the heading “Total Solids,” or in section 16.193 (dry sample), entitled “Kjeldahl Method” under the heading “Protein—Official Final Action.”

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in

section 16.059 (liquid sample), “Reese-Gottlieb Method [Reference Method] (11)—Official Final Action” under the heading “Fat,” or in section 16.199 (dry sample), entitled “Fat in Dried Milk (45)—Official Final Action.”

(iii) Ash content, maximum 7 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled “Ash (5)—Official Final Action” under the heading “Total Solids,” or in section 16.196 (dry sample), entitled “Ash—Official Final Action” under the heading “Dried Milk, Nonfat Dry Milk, and Malted Milk.”

(iv) Lactose content, maximum 85 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled “Gravimetric Method—Official Final Action” under the heading “Lactose,” or in section 31.061 (dry sample), entitled “Lane-Eynon General Volumetric Method” under the heading “Lactose—Chemical Methods—Official Final Action.”

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled “Moisture (41)—Official Final Action” under the heading “Dried Milk, Nonfat Dry Milk, and Malted Milk.”

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled “Method I—Official Final Action” under the heading “Total Solid.”

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled “Acidity (2)—Official Final Action” under the heading “Milk,” or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the “Food Chemicals Codex,” 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the